

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ )  
FENFLURAMINE/DEXFENFLURAMINE) ) MDL NO. 1203  
PRODUCTS LIABILITY LITIGATION )  
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THIS DOCUMENT RELATES TO: )  
SHEILA BROWN, et al. ) CIVIL ACTION NO. 99-20593  
v. )  
AMERICAN HOME PRODUCTS ) 2:16 MD 1203  
CORPORATION )

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8513

Bartle, C.J.

August 18, 2010

Gary Seat, Representative of the Estate of Linda Seat ("Mr. Seat" or "representative claimant"), a representative claimant under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust").<sup>2</sup> Based on the record developed in the show cause process, we must determine whether the representative claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>3</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Mr. Seat, Linda Seat's ("Ms. Seat" or "decedent") spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices  
(continued...)

To seek Matrix Benefits, a representative claimant<sup>4</sup> must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician who must answer a series of questions concerning the deceased's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In May, 2003, the representative claimant submitted a completed Green Form to the Trust signed by the attesting physician, Stephen Raskin, M.D., F.A.C.C. Based on an echocardiogram dated August 30, 1997, Dr. Raskin attested in

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3. (...continued)

(Matrix "A" and Matrix "B"), which generally classify for compensation purposes Diet Drug Recipients based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to the Diet Drug Recipient's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to representative claimants where the Diet Drug Recipients are diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

4. Under the Settlement Agreement, representative claimants include estates, administrators or other legal representatives, heirs or beneficiaries. See Settlement Agreement § II.B.

Part II of the Green Form that Ms. Seat suffered from severe mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial dimension, a reduced ejection fraction in the range of 50% to 60%, and ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise.<sup>5</sup> Based on such findings, claimant would be entitled to Matrix A-1, Level V benefits in the amount of \$1,078,927.<sup>6</sup>

Dr. Raskin also attested that claimant did not have mitral annular calcification. Under the Settlement Agreement, the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). As the Trust does not contest the representative claimant's entitlement to Level V benefits, the only issue before us is whether the representative claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In February, 2004, the Trust forwarded the claim for review by Ioannis P. Panidis, M.D., F.A.C.C., one of its auditing

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5. Dr. Raskin also attested that Ms. Seat suffered from mild aortic regurgitation, aortic stenosis, and New York Heart Association Functional Class III symptoms and underwent surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™. These conditions, however, are not at issue in this claim.

6. Under the Settlement Agreement, a claimant is entitled to Level V benefits if he or she otherwise qualifies for benefits at Matrix Level II, III, or IV and suffers from ventricular fibrillation or sustained ventricular tachycardia which results in hemodynamic compromise. See Settlement Agreement § IV.B.2.c.(5)(d).

cardiologists. In audit, Dr. Panidis concluded that there was no reasonable medical basis for Dr. Raskin's finding that Ms. Seat did not have mitral annular calcification. In support of this conclusion, Dr. Panidis explained that "[m]itral annular calcification [is] apparent on [the] apical four chamber view."

Based on the auditing cardiologist's finding that the decedent had mitral annular calcification, the Trust issued a post-audit determination that the representative claimant was entitled only to Matrix B-1, Level V benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), Mr. Seat contested this adverse determination.<sup>7</sup> In contest, Mr. Seat submitted a declaration from Dr. Raskin, who stated, in relevant part, that:

It is clear from the 8/30/97 study that mitral annular calcification ... is absent. This is because the echocardiographic features commonly associated with [mitral annular calcification] are not present. There are no bright reflections in the posterior AV groove associated with echo shadowing, nor evidence of the typical C-shaped morphology of [mitral annular calcification] between the papillary muscles in short axis, nor evidence of the echodense band seen throughout the cardiac cycle and parallel to the posterior wall by M-mode. The apical four chamber view demonstrates calcification located in the aortic valve and

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7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Seat's claim.

aortic annulus distinct from the posterior AV groove.

\* \* \*

Accordingly, I respectfully disagree with the Auditor's Opinion that the 8/30/97, echocardiogram, upon which the Linda S. Seat Green Form is based, reveals mitral annular calcification. It is my opinion that based on the commonly accepted definition of [mitral annular calcification], as evidenced in peer reviewed journals and authoritative textbooks, that there is insufficient evidence for a diagnosis of mitral annular calcification (MAC).

Claimant argued, therefore, that there was a reasonable medical basis for Dr. Raskin's Green Form attestations.

The Trust then issued a final post-audit determination, again determining that the representative claimant was entitled only to Matrix B-1, Level V benefits. Mr. Seat disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On August 26, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3879 (Aug. 26, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The representative claimant then served a response upon the Special Master. The Trust submitted a reply on

October 28, 2004. Under the Audit Rules it is within the Special Master's discretion to appoint a Technical Advisor<sup>\*</sup> to review claims after the Trust and the representative claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and the representative claimant, and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether the representative claimant has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding that Ms. Seat did not have mitral annular calcification. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in the Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the

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<sup>\*</sup> A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case, such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of the claim, Mr. Seat argues that "[w]hile the apical four chamber view does show a clinically insignificant amount of calcification located in the aortic valve and aortic annulus distinct from the posterior AV groove, the echocardiogram crucially does not show mitral annular calcification...." (emphasis in original). Mr. Seat also argues that the minimal amount of calcification "was not a factor in causing [Ms.] Seat's severe mitral regurgitation."

In response, the Trust argues that, under the Settlement Agreement, any amount of mitral annular calcification reduces a mitral valve claim to Matrix B-1. The Trust also contends that it is irrelevant whether mitral annular calcification was the cause of the decedent's mitral regurgitation.

The Technical Advisor, Dr. Vigilante, reviewed the echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Seat did not have mitral annular calcification. Specifically, Dr. Vigilante found that:

There was obvious mitral annular calcification noted on this study. This abnormality was characterized by significant increased reflectance and density of echoes in the annulus. [Mitral annular calcification] was noted in the posterolateral annulus as well as medially.

[Mitral annular calcification] was noted in the parasternal long axis view, parasternal short axis view, apical four chamber view, apical two chamber view, and subcostal view.

Dr. Vigilante further stated that "[a]n echocardiographer could not reasonably conclude that mitral annular calcification was not present on this echocardiogram."

In response to the Technical Advisor Report, Mr. Seat contends that "Dr. Vigilante's findings do not suffice to defeat the Seat claim because his report is focused on whether [mitral annular calcification] exists and fails to establish clinically relevant [mitral annular calcification] in Ms. Seat's case." (emphasis in original).

After reviewing the entire Show Cause Record, we find the representative claimant's arguments are without merit. Although the representative claimant relies upon Dr. Raskin's opinion that the decedent's "minimal calcification is of [a] degree irrelevant to Ms. Seat's severe [mitral regurgitation]," the Settlement Agreement provides that the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. Unlike some of the other factors that reduce a claim to Matrix B-1, any presence of mitral annular calcification, regardless of the amount, places the claim on Matrix B-1.  
Compare Settlement Agreement § IV.B.2.d.(2)(c)ii)d} with

Settlement Agreement § IV.B.2.d.(2)(c)i)d) ("Aortic root dilatation > 5.0 cm").<sup>9</sup>

Moreover, Mr. Seat's reliance upon Dr. Raskin's opinion that the presence of mitral annular calcification was irrelevant to Ms. Seat's mitral regurgitation is misplaced. Causation is not at issue in resolving Mr. Seat's claim for Matrix Benefits. Rather, Mr. Seat is required to show that he meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which the qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. If claimants or representative claimants are not required to demonstrate causation, the converse also is true; namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the regurgitation at issue. The Settlement Agreement clearly and

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9. For this reason as well, we reject Mr. Seat's argument that decedent's mitral annual calcification must be "clinically relevant."

unequivocally requires a claim to be reduced to Matrix B-1 if any amount of mitral annular calcification is present. We must apply the Settlement Agreement as written. Accordingly, Mr. Seat's argument that decedent's mitral annular calcification was not the cause of her mitral regurgitation is irrelevant.

For the foregoing reasons, we conclude that Mr. Seat has not met his burden of proving that there is a reasonable medical basis for finding that Ms. Seat did not have mitral annular calcification. Therefore, we will affirm the Trust's denial of this claim for Matrix A-1 benefits and the related derivative claim submitted by Ms. Seat's spouse.